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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:

PURDUE PHARMA L.P., *et al.*,

Debtors.¹

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Chapter 11

Case No. 19-23649 (RDD)

(Jointly Administered)

**NOTICE OF THE NAS CHILDREN AD HOC COMMITTEE'S
MOTION TO COMPEL DEBTORS TO PRODUCE DOCUMENTS**

PLEASE TAKE NOTICE, that on the NAS Children Ad Hoc Committee ("**NASG**"), through its counsel, Tarter Krinsky & Drogin LLP, respectfully submit this motion to compel production (the "**Motion**"), pursuant to Rule 2004 of the Federal Rules of Bankruptcy Procedure

¹ The Debtors in these cases, along with the last four digits of each Debtors' registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P. (0495), SVC Pharma L.P. (5717) and SVC Pharma Inc. (4014).

(the “**Rules**”), for entry of an order directing Debtors to produce all documents listed in the PKDM (Pharmacodynamics and Drug Metabolism)² attached hereto as **Exhibit A**, and for such other relief as the Court may deem just and proper. In support of this Motion, the NASG respectfully states as follows:

PRELIMINARY STATEMENT

1. This Motion is a model of specificity and precision. From over twenty-two million pages of materials the Debtors produced to the NASG and that it has analyzed and cataloged, the NASG is demanding that Debtors be compelled to produce to NASG the documents identified in the PKDM index in the manner maintained by the Debtors in the regular course of business, in native form and together with all associated metadata.

2. The NASG contends the PKDM is the database in which the Debtors maintain their non-clinical or pre-clinical toxicology studies in the regular course of business. In brief, the PKDM is a shared drive containing 3,758 opioid-related preclinical toxicology studies and related scientific information in Debtors’ possession, including studies provided to the FDA and studies not provided. The PKDM represents the Debtors’ non-clinical database and its production will provide the NASG and the Disclosure Oversight Board with unique one-of-a-kind detail concerning the Debtors’ scientific knowledge-base relating to aspects of the toxicology and efficacy of the Debtors’ opioid products. Of paramount importance is the fact the PKDM is organized by specific opioid compound and subject matter such that the NASG and scientific researchers will be able to efficiently navigate this collection of documents by either searching or browsing. For example, the following file path found in the PKDM indicates that

² Dr. Fanelli identified PKDM as “Pharmacodynamics and Drug Metabolism”. See Fanelli 10-12-2021 deposition at 207:13-19

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Producing these documents in the manner that Debtors' scientists access them will provide a usable collection of documents for scientists, physicians, graduate students and medical researchers utilizing the Public Document Repository or carrying out the research grants contemplated in the NAS Monitoring Trust.

3. As this Court is aware, the NASG represents the interests of guardians who are responsible for and entrusted with the care, welfare, and upbringing of children suffering from fetal opioid exposure due to maternal opioid exposure attributed to Debtors opioid products.

4. The Court is also aware the NASG has assumed an active and important role in these cases for an on behalf of their clients, in a manner that has been constructive, professional, and well-received. In fact, the actions and input of the NASG has been favorably recognized at various times by the Debtors, the UCC, the Mediators, and the Court.

5. By way of brief background, the NASG has successfully pursued and followed this Court's guidance in resolving three prior disputes: namely, a discovery motion to seek examination of Debtors' designated records custodian in accordance with the Bankruptcy Code and, thereafter, two (2) challenge letters concerning document designations, in accordance with the provisions found in the prevailing Protective Order.

6. For over two years, the NASG has diligently sought production of Scientific Information from Debtors, to better evaluate and communicate the actual depth and scope of Debtors' knowledge and understanding of the risks to the unborn child from fetal opioid exposure due to maternal use of Oxycontin and other Purdue opioid products.

7. In December 2020, the NASG sought previously undisclosed studies; specifically pre-clinical, clinical, non-Good Lab Practices (“non-GLP”), and good-laboratory practices (“GLP”) studies reporting on the effects of Purdue's opioid drugs during pregnancy and the potential risks to fetuses, including, fetal toxicity, mutagenicity and, generally, the effects of fetal opioid exposure and the medical diagnosis of NAS. *See* NASG’s initial Rule 2004 Motion to Debtors [Dkt. No. 2139] and its Reply [Dkt. No. 2538] (the “**NASG Discovery Motion**”). The NASG Discovery Motion was itself the product of many meet and confer sessions transpiring over many, many months.

8. A commonality to the NASG discovery is the production of medical and scientific information, research, data, studies, and materials (the “**Scientific Information**”) currently within the possession or control of the Debtors. Debtors Scientific Information is of both value and significance to:

- i. the NAS Monitoring Trust;
- ii. the Disclosure Oversight Board (the “**DOB**”);
- iii. fund administrators;
- vi. assisting parties (if necessary) with the claims administration process;
- vi. providing information that could further public health initiatives and objectives alike with the ongoing battle against maternal use of opioids and, more generally, the opioid epidemic;
- vii. medical researchers;
- viii. Bolstering the legal claims being brought by various parties in other pending opioid-related litigation throughout the country, which—in

turn—would inure to the public’s benefit by potentially leading to more settlements, litigation victories, and the much-needed money for opioid abatement, education and victim compensation;

- ix. millions of women burdened with the nagging question of whether they are flawed individuals and mothers or, rather, were they taken advantage of by Debtors in one form or another in downplaying and shading the risks of maternal opioid use and risks associated with fetal opioid exposure to an unborn child; and
- x. educating the public at large about Purdue’s and the Sackler’s role in the opioid crisis, with or without the public document repository.

9. The NASG is highly confident the Debtors have not fully produced to the NASG all of the materials demanded, including certain materials found in the PKDM.

10. In these cases, the NASG has already secured \$60 million in funding for the NAS Monitoring Trust (detailed in the Plan) that contemplates setting aside up to 5% of the trust’s corpus towards one or more grants “to research institutions to conduct and publish the results of research for helping children and families harmed, impacted or at risk of fetal opioid exposure. Grant recipients... will receive access to the... scientific documents of the Purdue Debtors and the IAC to the extent such scientific documents are part of a public record or in the public domain, **including documents related to preclinical toxicology.**” See ECF Doc. 3187, NAS Monitoring Trust at §5(a)(iv) (bold supplied). The NASG contends the PKDM clearly qualifies as “pre-clinical studies”, within the scope of the Plan.

11. The Plan also grants the DOB access to “documents obtained during the bankruptcy by the NAS Children Ad Hoc Committee regarding clinical and **pre-clinical studies conducted**

by the Debtors or other companies associated with the Sackler families.” See ECF Doc. 3726 at 92, Purdue Bankruptcy Plan at §5.12(f)(iv). (bold supplied). Here again, the PKDM clearly qualifies as “pre-clinical studies”, within the scope of the Plan.

JURISDICTION AND VENUE

12. This Court has jurisdiction over this matter under 28 U.S.C. §§ 157 and 1334. This matter is a core proceeding under § 157(b)(2).

13. Venue is proper under 28 U.S.C. §§ 1408 and 1409.

14. The bases for the relief requested herein are Bankruptcy Code section 105 and Bankruptcy Rules 2004, 9006 and 9016.

RELEVANT BACKGROUND

The Debtors’ Production Of Discovery To The NASG Is A Game of Cat-And-Mouse

15. The value of the information now sought by the NASG is, in many respects, underscored by Debtors’ discovery conduct with the NASG: a one-two combination of (1) document dump followed by (2) delay and dilatory conduct, lack of candor, obfuscation and blatant misrepresentations concerning the existence and accessibility of certain Scientific Information sought by the NASG. In many respects, the Debtors have used the discovery process to create barriers to overcome and, as a consequence, the scores of communications and numerous meet and confers concerning the PKDM has unfolded in slow motion, consuming more than one year. In the interim period, the NASG has appeared before the court to seek resolution of discovery disputes on three (3) separate occasions: the NASG filed in accordance with the bankruptcy code a motion to compel discovery (**NASG Discovery Motion**), followed by the NASG’s two separate

challenges to document designations in accordance with the terms of the prevailing Protective Order in these cases. It is noteworthy that on each occasion the NASG has produced constructive, pragmatic, and beneficial outcomes with the Debtors, without rancor and further delay. This motion is targeted on obtaining from Debtors just one item that can be traced to the NASG's initial discovery demands and, from that time forward, these items have been an agenda topic of scores of communications in addition to numerous meet and confers. Inexplicably and without justification, the Debtors are holding out from producing the PKDM. During the last meet and confer sessions the Debtors have been relying upon the outstanding appeal of the Plan as an excuse to further delay production of the PKDM.

16. It is important to know the Debtors kicked-off production to the NASG by producing an enormous quantity of documents, measuring over twenty-two million pages of data. Debtors accompanied this extraordinary production by grandly representing to the NASG that Debtors had produced everything when, in actuality, Debtors did not, and what was produced was haphazard, inefficient and merely a collection of documents produced in other litigation. Debtors' inattentiveness to production of materials to the NASG—in fact if not in name, a document/data dump—is manifested in the poor quality of text metadata; indeed, the NASG data platform had to re-perform optical character recognition on the entirety of documents in order to make Debtors' production searchable. In sum, Debtors knowingly produced information in a consciously deficient manner, adding considerable expense and delay to NASG.

17. Once the NASG obtained a handle on the quality, content, and comprehensiveness of the Debtors' document production, the Debtors commenced a game of cat-and-mouse to frustrate and delay the NASG in both locating and then confirming the existence of documents and

databases such as the PKDM and, as another example, the existence of Purdue's 'Central Repository, Stamford, CT'.

18. Following the Debtors most recent production, on January 30, 2022, of two never-before produced indexes of 510,774 documents³, the NASG identified several documents that have never been produced in any litigation. Debtors have been evasive regarding the NASG's revelation of the existence of these specific indexes of animal studies that seemingly had been excluded from the 22-million pages that Debtors had produced. To date, Debtors have explained to the NASG that 'they' (meaning, Debtors or its agents without specification) had "searched" the records and can report that some documents could not be located or, alternatively, were too burdensome to retrieve. NASG contends the information is readily identifiable and accessible, and its production in full is not unduly burdensome. It is worth repeating that this one index confirms the existence of numerous studies, *the very same studies that Debtors had steadfastly claimed could not be located by them or, alternatively, are too onerous to retrieve.*

19. The NASG has also determined beyond a reasonable doubt that Debtors knew of the existence and whereabouts of the PKDM at all times relevant. Debtors deliberate dilatory conduct resulted in delaying discovery to the NASG that, in turn, undermined and interfered with the NASG's access to Scientific Information that would have proven useful in these cases, and in Mediation in demonstrating the full extent of risks and injuries to the unborn child from fetal opioid exposure due to maternal opioid use attributed to Debtors' opioid products, as well as for purposes of negotiating, quantifying and allocating damages among the unsecured creditors in an equitable manner.

³ Another index, known as the Veeva Vault, has also been identified and has appeared as both the subject of NASG-Debtor communications as well as an agenda item of meet and confers; however, it is not the subject of this Motion

20. Inexplicably and without justification, Debtors refused to diligently search for documents responsive to the NASG's discovery requests and, instead, have seemingly squandered Estate assets to repel and delay the NASG at every turn.

Debtors Have Slow-Walked Discovery

21. On January 26, 2021, in response to NASG's discovery efforts, Debtors produced a document collection comprising of 2.6 terabytes (approximately 2,600,000 megabytes) of data that Debtors purport is responsive to NASG's discovery requests for previously undisclosed Scientific Information. Notwithstanding the NASG's narrow discovery requests to Debtors, the amount of digital information Debtors had produced in response was so large that Debtors were constrained to ship by regular U.S. mail two separate external hard drives. However, there were numerous problems with Debtors' mass production of data; including flawed OCR, file transfer difficulties, and Debtors' inclusion of a massive number of extraneous and irrelevant documents. Undaunted, the NASG employed advanced data analysis techniques to evaluate and examine the contents of Debtors' unprecedentedly large data dump.

22. NASG utilized AI machine learning to analyze known relevant documents and identify additional search terms to further drill into the production and identify relevant studies. Ultimately, 148 terms were searched, 68 of which were generated using predictive coding. Even with the use of advanced data analysis techniques, review of the massive collection required the assignment of seven staff.

23. Additionally, the NASG determined the existence of an index of the scientific studies being stored at a facility owned and operated by Iron Mountain, a well-recognized document storage and management vendor that Purdue had retained. The revelation of storage facilities like Iron Mountain, and Central Repository, Stamford, CT., containing the exact type of

information the NASG has been requesting from the inception—coupled with Debtors’ baseless denial that a trove of scientific information exists or similarly had been maintained at the Central Repository, Stamford CT—has served to undermine Debtors’ credibility, probity, and honesty.

24. Dr. Fanelli, Purdue Director of Regulatory Affairs until 2017, testified during his 30(b)6 deposition that Purdue did in fact possess a centralized regulatory database of all materials related to FDA and other regulatory submissions. Fanelli testified that this regulatory database could be searched and would contain all clinical (human) studies and non-clinical (animal) studies that were included as part of regulatory submissions. Fanelli testified there was also a "non-clinical" database which contained all toxicology studies including those that **were maintained by Purdue but not included as part of FDA/regulatory submissions.** (See **Exhibit B**, Fanelli 10-12-2021 Deposition Excerpts, Fanelli deposition, at 51:20-52:24, 59:5-60:12, 62:4-63:6). Upon information and belief, the PKDM is the non-clinical database Fanelli referred to.

25. To summarize, the NASG is seeking production of all documents listed in the index designated as the PKDM, as they fall within the scope of our initial requests from December of 2020: *“All Preclinical Toxicology Studies, including but not limited to reproductive toxicology, mutagenicity, genotoxicity, chromosomal [aberrations], dose-ranging, exploratory, investigative or non-GLP studies regarding opioids in the possession of the Debtor(s) that have not been disclosed to the FDA”*. (See Dkt. Nos. 2139 and 2538, NASG Discovery Motion) .

26. Full and comprehensive discovery of Scientific Information has the salutary purpose of assessing wrongdoing of the Debtors and affiliated entities that has occurred in what purports to be conscious misrepresentation and concealment of scientific evidence related to maternal opioid use and potential risks to the fetus. Similarly, Debtors’ entitlement to

confirmation of the Plan was predicated upon Debtors' honesty and probity in all matters in these cases, including full and honest production in good faith in all respects.

27. The discovery sought in this Motion is consistent with a long-running effort to assist a party in interest in determining the nature and extent of one of Debtors' varied assets—its Scientific Information related to fetal opioid exposure—an asset that, oddly, remains unaccounted for, and, consequently, its value, currency, and noteworthiness remain locked.

28. Attached hereto as **Exhibit C** is the index of PKDM which Debtors produced to NASG. The NASG requests production of the documents reflected in the PKDM index.

29. Without timely disclosure, a critical one-of-a-kind collection of records arising from the Debtors' (in concert with other members of the pharmaceutical industry) testing for and identifying the dose-response, toxic, teratogenic, genotoxic, metabolic, and mutagenic impact of opioid exposure on mammals and the frequency and scope of the injuries to the adult, newborn and embryonic test animals will remain locked away. Without the remedy sought by this motion, these irreplaceable records will remain hidden from the NASG, medical investigators, and scientific researchers alike and, most probably, cause unnecessary delays in developing, understanding, and contextualizing follow-up studies researching injuries caused by and related to embryonic opioid exposure. Without timely disclosure in these cases, these crucial records stand to remain hidden from the NASG, medical investigators, among others, all of whom are diligently pursuing clues to identify and treat the harms associated with in utero opioid exposure to opioids, affecting literally hundreds of thousands, perhaps millions, of children, as is now widely reported.

30. The NASG and the Debtors have, until recently, mutually and diligently continued their discussions of the discovery requests that remain unresolved leading up to this Motion, and

the NASG is amenable to a full resolution without further motion practice. The NASG is clearly entitled to the requested discovery from the Debtors in these cases, and production is not unduly prejudicial to any party and production at this juncture in the cases is both fair and reasonable under the totality of the circumstances.

31. The sole discovery request, attached as **Exhibit C**, seeks specific medical and scientific information and documents that may be relevant, or may lead to discovery of relevant information, regarding or relating to the issues of the adequacy of, *inter alia*, Debtors' warnings regarding the full extent of the potential risks—to pregnant women and women of childbearing ages alike—of using opioids during pregnancy.

32. The nature of the documents reviewed thus far, it is argued, demonstrate that Purdue downplayed and minimized known risks of fetal opioid exposure; misrepresented the data from animal studies; seemingly engaged in joint efforts with other manufacturers to mislead regulators; and ignored peer-reviewed studies that could have the effect of adversely impacting and suppressing opioid prescriptions to women of child bearing age.

RELIEF REQUESTED

33. The NASG respectfully requests that the Court enter an order, pursuant to Bankruptcy Rule 2004, substantially in the form of the proposed order attached hereto as **Exhibit A**, and an example of the buprenorphine worksheet lines 143-153 is included with Exhibit A for exemplary purposes.

34. Admittedly, under Federal Rule of Bankruptcy Procedure 9018, the court may, either on formal motion or upon its own initiative (*sua sponte*), seek to protect matters that are

secret, confidential, scandalous, or defamatory. The information and data contained in the scientific studies relating to the PKDM that Debtors are improvidently withholding from the NASG is not in any respect secret, confidential, scandalous or defamatory, rendering Rule 9018 inapplicable. The same Scientific Information, however, has the potential of conferring profound and extraordinary value and benefit to the NASG, and to the NAS Monitoring Trust, in terms of providing NAS Monitoring Trust with a rich, vital, unrivaled and irreplaceable source of medical data and materials to build upon. This same information and data may also provide the clues the NASG, scientists, and researchers have been looking for in their noble efforts to unlock unresolved medical mysteries surrounding the potentially life-threatening birth outcomes associated with fetal opioid exposure due to maternal opioid use. Apart from the expressed needs of a party, the NASG, the U.S. Supreme Court has held that documents and testimony related to important historical events may remain sealed only if competing interests outweigh the public's need for access to these documents and testimony. See *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 98 S. Ct. 1306, 55 L. Ed. 2d 570 (1978). Debtors' cases have attained historical significance, whereby the public has an undeniably important, rational, and compelling need to obtain access to previously undisclosed documents addressing risks to fetal development from opioid use during pregnancy.

35. Documents produced thus far indicate the Debtors seemingly continue to conceal, without justification, toxicological information and data relating to deformities, congenital malformations, increased infant test animal deaths, decreased infant test animal birth weights, chromosomal aberrations, teratogenic potential, increased genotoxicity, including written admissions that animal studies show reproductive toxicological effects.

36. Disclosure of the contents of the PKDM will serve to close gaps in medical knowledge not only for the purposes of the NASG, but also for the benefit of research scientists

and medical experts for the future prevention of in utero exposure to opioids and children born suffering with NAS.

BASIS FOR RELIEF

37. Bankruptcy Rule 2004(a) provides, in relevant part, that a party-in-interest (such as the NASG) may request discovery related to “acts, conduct, or property, or to the liabilities and financial condition of the debtor, or to any matter which may affect the administration of the debtors’ estate or to the debtors’ right to a discharge.” Fed. R. Bankr. P. 2004(b). The NASG’s request for production of the PKDM fits within the ambit of the Rule.

38. The purpose of Bankruptcy Rule 2004 is to “assist a party in interest in determining the nature and extent of the bankruptcy estate, revealing assets, examining transactions and assessing whether wrongdoing has occurred.” *In re Recoton Corp.*, 307 B.R. 751, 755 (Bankr. S.D.N.Y. 2004). Rule 2004 permits discovery “to determine the extent of the estate’s assets and recover those assets for the benefit of creditors.” *In re Madison Williams & Co., LLC*, No 11-15896, 2014 WL 56070, at *3 (Bankr. S.D.N.Y. Oct. 30, 2014) (“The underlying purpose of Rule 2004 is to ‘allow the court to gain a clear picture and whereabouts of the bankrupt’s estate.’” (quoting *Keene Corp. v. Johns-Mansville Corp. (In re Johns-Manville Corp.)*, 42 B.R. 362, 364 (S.D.N.Y. 1984))). From the outset, the NASG has diligently sought Scientific Information from the Debtors, and this Motion is consistent with this objective.

39. The scope of discovery allowed under Bankruptcy Rule 2004 is ““very broad and great latitude of inquiry is ordinarily permitted.”” *In re Madison Williams*, 2014 WL 56070, at *3 (quoting *In re Wilcher*, 56 B.R. 428, 433 (Bankr. N.D. Ill. 1985)). Courts have repeatedly recognized that discovery provided for under Rule 2004 encompasses “broader discovery than is

available under the Federal Rules of Civil Procedure.” *In re: Bernard L. Madoff*, 2014 WL 5486279, at *2 (citing *In re Recoton Corp.*, 307 B.R. at 755); *see also In re Hughes*, 281 B.R. 224, 226 (Bankr. S.D.N.Y. 2002) (“[T]he scope of examination allowed under Rule 2004 is broader than discovery allowed under the Federal Rules of Civil Procedure”); *In re Drexel Burnham Lambert Grp., Inc.*, 123 B.R. 702, 711 (Bankr. S.D.N.Y. 1991).

40. While the NASG has engaged in good faith discussions with the Debtors regarding the discovery, the NASG, nonetheless, is availing itself of the formal protections of a Rule 2004 Order in the course of properly bringing a discovery dispute before the Court.

COMPLIANCE WITH THE RULES

41. This Motion includes citations to the applicable rules and statutory authorities upon which the relief requested herein is predicated, together with a discussion of their application to this Motion. The NASG respectfully submits this Motion satisfies Rule 9013-1(a) of the Local Bankruptcy Rules for the Southern District of New York.

NOTICE

42. The NASG has duly provided informal notice of this Motion to the Debtors. The NASG notified the Debtors of their intention to file this Motion by letter (the “**Meet and Confer Request Letter**”), and a true and correct copy is attached hereto as **Exhibit D.**

NO PRIOR REQUEST

43. No prior request for the relief sought in this Motion has been made in these cases.

RESERVATION OF RIGHTS

44. The NASG and its members reserve all their respective rights, claims, defenses and remedies, including, without limitation, the right to amend, modify or supplement this Motion, to seek additional discovery, add additional parties, or to raise additional grounds for granting this Motion during any hearing on the Motion.

CONCLUSION

45. The NASG respectfully requests the Court enter an Order, substantially in the form of **Exhibit A**, attached hereto, compelling Debtors to produce the PKDM in the manner described therein, and for such other and further relief as the Court may deem just, proper and equitable.

Dated: May 25, 2022
New York, New York

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